

### **REMARKS**

Applicants have received and reviewed the Final Office Action mailed July 15, 2008. Currently, claims 17, 19, and 39-62 are pending, of which all stand finally rejected. Reconsideration and reexamination are respectfully requested.

#### **Claim Rejections Under 35 U.S.C. §112**

On page 2 of the Final Office Action, claims 47-56 and 62 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner states, "At the time the application was filed, the applicant failed to disclose that after expansion of the bulge portion, 'a portion of the bulge portion is positioned within the circumferential plane.'" Applicants respectfully traverse the rejection.

As the Examiner is aware, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.' *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed." (See MPEP § 2163.02). Furthermore, "[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement". (See MPEP § 2163.02). Applicant must respectfully assert that the application as filed clearly conveyed to a person of ordinary skill in the art that Applicant possessed the limitations noted by the Examiner above. For example, page 11, lines 11-15, recites "However, in at least one embodiment, balloon 30 also includes a unique geometry which in the expanded configuration, comprises a bulge region 34 that would effectively push against members 24 to push the members 24 outward from the stent body 12 to expand the members

24 to expand outward to form the scaffold 14". Clearly, this passage teaches that "a portion of the bulge portion is positioned within the circumferential plane". Furthermore, other passages of the specification as filed along with the Figures as filed, clearly convey to a person of skill in the art that Applicant possessed the limitation "a portion of the bulge portion is positioned within the circumferential plane" when the Application was filed. Therefore, Applicant believes that claims 47-56 and 62 comply with the written description requirement of § 112, first paragraph, and withdrawal of the rejection is respectfully requested.

### **Claim Rejections Under 35 U.S.C. §103**

On page 3 of the Final Office Action, claims 17, 19, 39, 40, 46, 57, 58, and 61 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi et al. (US 6,325,826). After careful review, Applicants must respectfully traverse the rejection.

Turning to claim 17, which recites:

17. (Previously Presented) A system comprising:

only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, each of the moveable members being moveable independent of the other moveable members, the stent body being expandable from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body, in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall to form a scaffold, the scaffold defining a side opening in the stent wall.

Nowhere does Lam or Vardi et al., either alone or in combination, appear to teach or suggest "the single catheter having only a single balloon" and "in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall to form a scaffold, the scaffold defining a side opening in the stent wall", as recited in claim 17.

Instead, Lam appears to teach an ostial stent having a tubular body and a deformable flaring portion. The deformable flaring portion, however, appears to be disposed at an end of the stent, in contrast to claim 1, which recites “the scaffold defining a side opening in the stent wall”. The deformation of the flaring portion appears to be accomplished by expanding a balloon or a series of balloons that extend out the end of the stent. Nothing in Lam appears to teach or suggest “a portion of the plurality of movable members being extended radially outward from the stent wall to form a scaffold, the scaffold defining a side opening in the stent wall”, as recited in claim 17.

The Examiner then relies on Vardi et al. as teaching the scaffold defining a side opening in the stent wall, such that a portion of the movable members expand towards a proximal end of the stent body and a portion of the movable members expand towards a distal end of the stent body. In combining the teachings of Vardi et al. with Lam in an attempt to show the claimed invention is obvious, the Examiner states “It is well known within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results”. While Applicant does not contend the Examiner’s assertion, Applicant respectfully asserts that nothing in Lam or Vardi et al. appears to teach or suggest a technique for expanding scaffold defining a side opening in the stent wall. As such, there is clearly no known technique taught by the cited references that can be applied to the other cited reference to arrive at the claimed invention and, thus, there is clearly no *prima facie* case of obviousness.

Furthermore, Applicants remind the Examiner that “[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious”...The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” (See MPEP § 2141). Further, the Supreme Court in *KSR Int’l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art.” See page 14 of the April 30, 2007 decision. As such, the Examiner is required to provide clearly articulated reasons why the individual elements would be obvious to combine. In the Final Office Action, the Examiner merely stated:

It is well known within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the movable members on a side wall, such that the radially expand to from a scaffold defining a side opening in the stent wall as taught by Vardi. Do so would provide the stent the ability to be positioned across the bifurcation with the side opening positioned over the bifurcation point.

However, this statement fails to provide any articulated reasons why a side opening in a stent is obvious in a single balloon catheter system, as neither reference appears to teach or suggest such a system or a system capable of such a technique. Therefore, for at least these reasons, claim 17 is clearly patentable over Lam and Vardi et al. For similar reasons and others, claims 19, 39, 40, and 46, which depend from claim 17 and include additional limitations, are clearly patentable over Lam and Vardi et al. and withdrawal of the rejection is respectfully requested.

Turning to claim 57, which recites:

57. (Previously Presented) A catheter system comprising:

a catheter having an balloon arrangement, the balloon arrangement including an elongate body portion; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, the movable members configured as self expandable structures that move from an unexpanded position retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall when activated by expansion of the stent wall, at least a portion of the moveable members expanding towards a proximal end of the stent body and at least a portion of the moveable members expanding towards a distal end of the stent body.

For similar reasons discussed above, as well as others, claim 57 is clearly patentable over Lam and Vardi et al. For similar reasons and others, claim 58, which depends from claim 57 and includes additional limitations, is clearly patentable over Lam and Vardi et al. and withdrawal of the rejection is respectfully requested.

Turning to claim 61, which recites:

61. (Previously Presented) A catheter system, comprising:

only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall and movable between an unexpanded position within the circumferential plane and an expanded position extending radially outward from the circumferential plane to define an aperture in the circumferential wall, the single balloon extending within the stent body from at least a distal end

to at least a proximal end of the stent wall, the stent wall and the movable members being expandable by expansion of the single balloon, wherein a first moveable member extends radially outward at a location distal of the aperture in the circumferential wall and a second moveable member extends radially outward at a location proximal of the aperture.

For at least the reasons discussed above, neither Lam nor Vardi et al., either separately or in combination, appear to teach or suggest the claimed invention of claim 61. Therefore, for at least these reasons, claim 61 is clearly patentable over Lam and Vardi et al.

On page 4 of the Final Office Action, claims 41-45, 59 and 60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi et al. (US 6,325,826), and further in view of Crocker et al. (US 5,843,116). After careful review, Applicants must respectfully traverse the rejection. For at least the reasons discussed above, claims 17 and 57 are believed to be clearly patentable over Lam and Vardi et al. and nothing in Crocker et al. appears to remedy the above-noted shortcomings of Lam and Vardi et al. Therefore, claims 41-45, 59 and 60, which depend from claims 17 and 57 and include additional limitations, are believed to be clearly patentable over Lam, Vardi et al., and Crocker et al. and withdrawal of the rejection is respectfully requested.

On page 5 of the Final Office Action, claims 47-56 and 62 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi et al. (US 6,325,826) in view of Marotta et al. (US 6,261,305). After careful review, Applicants must respectfully traverse the rejection.

Turning to claim 47, which recites:

47. (Previously Presented) A catheter system comprising:

a catheter having a balloon arrangement, the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded, the bulge portion being positioned at a location between a proximal end and a distal end of the body region and positioned at a predetermined circumferential location around a circumference of the body region, the bulge portion extending around less than an entire circumference of the body region; and

a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, at least one of the moveable members being separate from the other moveable members, the stent wall being expandable from an unexpanded condition to an expanded condition by expansion of the body portion of the balloon arrangement, and the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent, wherein the bulge portion is positioned within the circumferential plane prior to expansion of the bulge portion, and after expansion of the bulge portion a portion of the bulge portion is positioned within the circumferential plane and a portion of the bulge portion extends radially through the side opening outside the circumferential plane.

Nowhere do Vardi et al. or Marotta et al. appear to teach or suggest “the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded” and “the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent”, as recited in claim 47.

In the Final Office Action, the Examiner appears to rely on Marotta et al. as teaching or suggesting “the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded”. However, Marotta et al. appears to teach an endovascular prosthesis wherein a leaf portion moves away from the tubular plane of the body 105 as the body is flexed upon navigation into a secondary artery. However, nothing in Marotta et al. appears to teach or suggest a balloon

arrangement including a bulge portion configured to protrude radially outward from the body portion when expanded to expand the movable members of the bifurcated stent to a position extending radially outwardly from the stent wall to define a side opening in the stent. Furthermore, as discussed above, the Examiner has failed to provide any articulated reasoning with some rational underpinning why the device of claim 47 is obvious in view of the cited references. Therefore, for at least these reasons, claim 47 is clearly patentable over Vardi et al and Marotta et al. For similar reasons and others, claims 48-56, which depend from claim 47 and include additional limitations, are clearly patentable over Vardi et al and Marotta et al. and withdrawal of the rejection is respectfully requested.

Turning to claim 62, which recites:

62. (Previously Presented) A system comprising:

- only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a first body vessel and advancement to a vessel bifurcation site at which a second body vessel branches from the first body vessel; and

- a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, the stent body being expandable from an unexpanded condition to an expanded condition-by expansion of the single balloon within the stent wall, in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall and into the second body vessel to form a scaffold, the scaffold defining a side opening in the stent wall and a conduit into the second body vessel;

- wherein the single balloon comprises an elongate body region and a bulge region protruding radially outward from the body region when expanded, the bulge region extending around less than an entire circumference of the body region, in the unexpanded state the stent wall being disposed about the body region and the plurality of movable members positioned over the bulge region;

- wherein the bulge region is positioned on an exterior surface of the body region between proximal and distal ends of the body region; and

- wherein the bulge portion is positioned within the circumferential plane prior to expansion of the bulge portion, and after expansion of the bulge portion a portion of the bulge portion is positioned within the circumferential plane and a portion of the bulge portion extends through the side opening radially outside the circumferential plane.

For at least the reasons discussed above, neither Vardi et al. nor Marotta et al., either alone or in combination, appear to teach or suggest a catheter system as currently claimed. Therefore, for at least these reasons, claim 62 is clearly patentable over Vardi et al and Marotta et al. and withdrawal of the rejection is respectfully requested.

**Conclusion**

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
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By their Attorney,

Date: \_\_\_\_\_

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